DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/714,549, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claim 1-26 and 60-63 contain the limitation, "said proximal main member having a distally extending threaded recess in a proximal surface thereof...". This limitation is not supported in application No. 09/714,549. Therefore, claims 1-26 and 60-63 do not meet the conditions for the benefit of the filing date of 11/16/2000 of application No. 09/714,549. Claims 1-26 and 60-63 have an effective filing date of 3/29/2004.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-26, 60-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-26, 60-63 contain the limitation, "said proximal main member having a distally extending threaded recess in a proximal surface thereof...". This limitation was not disclosed in the application as originally filed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

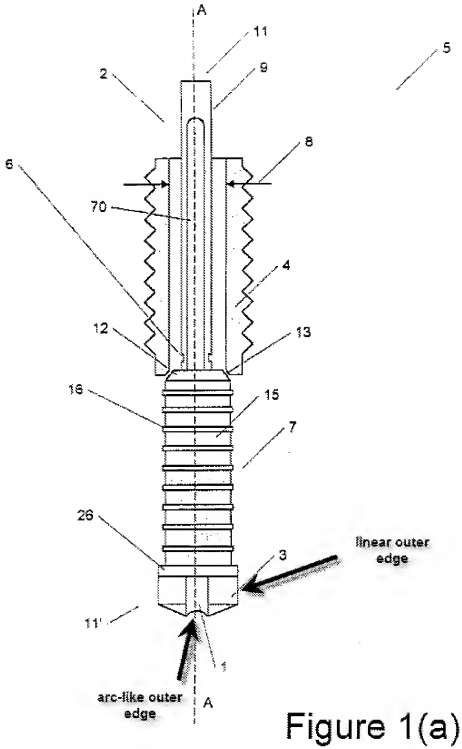
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 29-37, 39, 40, 41, 43, 45-50, 52-58 are rejected under 35 U.S.C. 102(b) as being anticipated by McDevitt et al. (Pat. No. US 5,935,129).

Regarding claims 29-37, 39, 40, 41, 43, 45-48, McDevitt et al. discloses an apparatus for attaching tissue to bone comprising: an expandable body 4 (figures 5a-5c)

configured to expand into bone (figures 5a-5c), said expandable body 4 defining a bore 14 (figure 2); an expander pin 7 (figure 4a) comprising a shaft sized to be received in the bore 14 of said expandable body 4 (figure5b) and expand said expandable body 4 laterally when said expander pin 7 is driven into said expandable body 4 (col. 9, lines 58-67); and a tissue attachment member (laterally extended region 3 or "slot" 70 (figure 1a) for holding suture 60 (figure 5a)) formed on said shaft (figure 1a; col. 4, lines 16-33); whereby when said expander pin 7 is driven into said expandable body 4, said expandable body 4 is attached to the bone and said tissue attachment member 70 secures the tissue to said apparatus (via suture 60). The expander pin 7 includes a fastener stabilization apparatus16 (figure 1a; col. 4, lines 51-54) for stabilizing the expander pin 7 relative to the expandable body 4. The fastener stabilization apparatus 16 comprises threads or ribs (col. 4, lines 51-54). The tissue attachment member comprises at least one laterally-extending projection 3 (figure 1a) for tacking tissue (i.e., a ligament graft inserted in the bone hole). The at least one laterally-extending projection 3 has a substantially linear outer edge (figure 1a). The at least one laterally-extending projection 3 has a substantially arc-like outer edge (figure 1a). The tissue attachment member comprises a bore 70 formed in said expander pin 7 and a suture 60 extending through said bore 70 formed in said expander pin 7 (figure 5a). The tissue attachment member is configured so that said suture is slidable relative to said expander pin 7 when said expander pin 7 is received in said expandable body 4 (col. 5, lines 15-48). The expander pin 7 has indicia 6 for indicating depth (frangible portion 6 is capable of indicating to the user when the pin has been fully seated in the expandable

member (figure 5c). The expandable body 4 is provided with a tapered distal end (figures 5a-5b). The expandable body comprises a distal tip member 32 (figures 5a-5b) and a proximal main member 4, said distal tip member 32 being separable from said proximal main member 4 (figure 5a). The distal tip member 32 and the proximal main member 4 are frictionally interengageable with one another (col. 9, lines 56-67). The distal tip member 32 is tapered (in its deployed configuration, figure 5c). The expandable body 4 includes a bone securement apparatus 53 (figure 2; col. 6, lines 39-49) for securing the expandable body 4 relative to bone (col. 6, lines 39-49). The bone securement apparatus 53 comprises ribs or threads (col. 6, lines 39-49).


A
11
5
2
9
8
6
70
4
12
13
16
15
7
26
3
linear outer edge
11'
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arc-like outer edge
A

Figure 1(a)

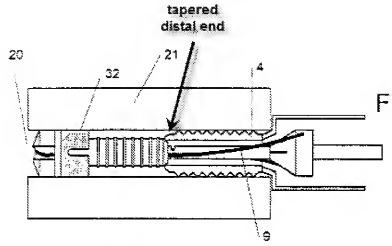

Figure 5(a)

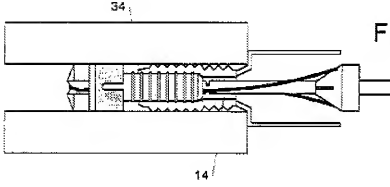

Figure 5(b)

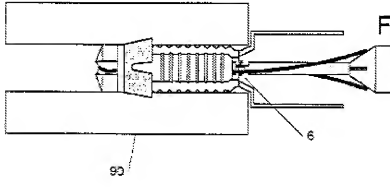

Figure 5(c)

Regarding claims 29, 49, 50, 52-58, McDevitt et al. discloses an apparatus for attaching tissue to bone comprising: an expandable body 4 (figure 1b) configured to expand into bone, said expandable body 4 defining a bore 14 (figure 2); an expander pin 51 (figure 1b) comprising a shaft sized to be received in the bore 14 of said expandable body 4 (figure 1b) and expand said expandable body 4 laterally when said expander pin 51 (col. 5, lines 49-57) is driven into said expandable body 4 (col. 5, lines 49-57); and a tissue attachment member 26 formed on said shaft (figure 1b); whereby when said expander pin 51 is driven into said expandable body 4, said expandable body 4 is attached to the bone and said tissue attachment member 26 secures the tissue to said apparatus (flange 26 is capable of securing tissue to the apparatus, i.e., a ligament graft disposed in the bone hole or any tissue that might adhere to the material that flange 26 is made of). The apparatus further comprises an installation tool "deployment device" (col. 7, lines 9-56), and wherein said installation tool comprises a shaft 2 sized to be slidingly received in said bore 14 of said expandable body 4 (figure 1b) and a bore of said expander pin 51 (figure 1b). The shaft 2 is releasably attachable to said expandable body 4 (via frangible portion 6; col. 8, lines 11-22). The shaft 2 is provided with a tapered distal end 3 (figure 1b). The shaft 2 extends distally beyond the expandable body 4 when the shaft 2 is slidingly received in the bore of the expandable body 4 (figure 1b, figures 3a-3c). The apparatus further comprises a pusher member 64 (figure 3a; col. 7, lines 9-56) configured to drive said expander pin 51 into said expandable body 4 (col. 7, lines 9-56). The pusher member 64 slides along said shaft 2 when driving said expander pin 51 into said expandable body 4 (col. 7, lines 9-56). The

apparatus further comprises a cannulated driver assembly "deployment device" adapted to drive said expander pin 51 into said expandable body 4 (col. 7, lines 9-56). The cannulated driver assembly slides along a shaft 2 connected to said expandable body 4 (figures 3a-3b). The cannulated driver assembly includes a trigger "pistol grip/handle" (col. 7, lines 42-56) for inducing the driving of said expander pin 51.

6. Claims 29, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Choung (Pat. No. US 6,332,778 B1).

Regarding claims 29, 41, and 42, Choung discloses an apparatus for attaching tissue to bone comprising: an expandable body 10/50 (figure 2) configured to expand into bone, said expandable body 10/50 defining a bore (figure 2); an expander pin 30 (figure 2) comprising a shaft sized to be received in the bore of said expandable body 10 (figure 2) and expand said expandable body 10 laterally when said expander pin 30 is driven into said expandable body 10 (col. 5, lines 42-51); and a tissue attachment member "threads" formed on said shaft (figure 2); whereby when said expander pin 30 is driven into said expandable body 10, said expandable body 10 is attached to the bone and said tissue attachment member "threads" secures the tissue to said apparatus (since the device has slots (figure 1), cells and tissue can migrate into the device and attach to the threads of the pin 30). The expandable body comprises a distal tip member 50 (figure 2) and a proximal main member 10 (figure 2) and the distal tip member 50 and proximal main member are separable and threadedly interengageable with each other (col. 4, lines 4-6).

7. Claims 29, 56, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Johanson et al. (Pat. No. US 7,074,203 B1).

Regarding claims 29, 56, and 59, Johanson et al. discloses an apparatus for attaching tissue to bone comprising: an expandable body 4 (figure 2) configured to expand into bone, said expandable body 4 defining a bore 19 (figure 1); an expander pin 6 (figures 1 and 2) comprising a shaft sized to be received in the bore 19 of said expandable body 4 (figures 1 and 2) and expand said expandable body 4 laterally when said expander pin 6 is driven into said expandable body 4 (figure 2); and a tissue attachment member 11 formed on said shaft (figure 2); whereby when said expander pin 6 is driven into said expandable body 4, said expandable body 4 is attached to the bone and said tissue attachment member 11 secures the tissue to said apparatus (figure 2). The apparatus further comprises a cannulated driver assembly 26 (figure 6) comprising a slap hammer 32 (figure 6) adapted to drive the expander pin into the expandable body (col. 6, lines 1-12; figures 6-9)

8. Claims 29, 49, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Lizardi (Pat. No. US 6,641,596).

Regarding claims 29, 49, and 51, Lizardi discloses an apparatus for attaching tissue to bone comprising: an expandable body 20 (figure 2) configured to expand into bone, said expandable body 20 defining a bore 22 (figure 2); an expander pin 60 (figure 2) comprising a shaft sized to be received in the bore 22 of said expandable body 20 (figure 2) and expand said expandable body 20 laterally when said expander pin 60 is driven into said expandable body 20 (figure 2A); and a tissue attachment member 66

(figure 2A) formed on said shaft (a suture could extend through bore 66 and attach tissue to the device); whereby when said expander pin 60 is driven into said expandable body 20, said expandable body 20 is attached to the bone and said tissue attachment member 66 secures the tissue to said apparatus. The apparatus further comprises an installation tool 200 (figure 2), and wherein said installation tool comprises a shaft 214 (figure 2) sized to be slidingly received in said bore 22 of said expandable body 20 (figure 2) and a bore 66 of said expander pin 60 (figure 2). The shaft and the expandable body are threadedly interengageable with each other (figure 2).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-5, 7, 12-17, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (Pat. No. US 6,332,778 B1) in view of McDevitt et al. (Pat. No. US 6,319,252).

Regarding claims 1-5, 7, 12-17, and 44, Choung discloses an apparatus for attaching tissue to bone comprising: an expandable body 10/50 (figure 2) defining a bore (figure 2) and configured to expand into bone, said expandable body 10/50 comprising a distal tip member 50 and a proximal main member 10, said distal tip member 50 being of harder material than said proximal main member, said distal tip

member 50 having a threaded recess 54 (figure 2) in a proximal surface thereof and said proximal main member 10 having a distally extending threaded recess 22 (figure 2) in a proximal surface thereof and said proximal main member 10 having a distally extending threaded projection 11 (figures 2 and 3) threadedly interengageable with the distal tip member recess (figure 2); an expander pin 30 (figure 2) comprising a shaft sized to be received in the bore of said expandable body 10 and expand said expandable body 10 laterally when said expander pin 30 is driven into said expandable body 10 (col. 5, line 64 – col. 6, line 2); and a tissue attachment member (threads, figure 2) formed said shaft (cells and tissue can migrate into the device and attach to the threads of the pin 30); whereby when said expander pin 30 is driven into said expandable body 10, said expandable body 10 is attached to the bone and said tissue attachment member secures the tissue to said apparatus (col. 5, lines 51-61). The expander pin includes a fastener stabilization apparatus 60 (figure 2) for stabilizing said expander pin 30 relative to said expandable body 10. The fastener stabilization apparatus 60 comprises threads (figure 2) and ribs 64 (figure 4). The tissue attachment member comprises at least one laterally-extending projection "threads" for tacking tissue (figure 2). The at least one laterally-extending projection "threads" has a substantially arc-like outer edge (figure 2). The expandable body distal tip member 50 is tapered (figure 2). The expandable body 10 includes a bone securement apparatus 12 (figure 2) for securing said expandable body 10 relative to bone (col. 5, lines 51-61). The bone securement apparatus comprises threads/ribs 12 (figure 2). The apparatus further comprises an installation tool "desired instrument" (col. 5, lines 34-35), and

wherein said installation tool comprises a shaft sized to be slidingly received in said bore of said expandable body 10 and in a bore (phillips head screw driver mating portion, figure 1) of said expander pin 30. The shaft is releasably attachable to said expandable body 10 (figure 1).

Choung does not disclose that the distal tip member is of a harder material than the proximal main member.

McDevitt et al. teaches an apparatus wherein the distal tip member 160 is made of a harder material than the proximal main member 165 for the purpose of helping to form the passageway in the bone (col. 4, lines 49-61).

It would have been obvious to one skilled in the art at the time the invention was made to make the distal tip member of a harder material than the proximal main member in order to help the distal tip member form the passageway in the bone while allowing the device to expand as taught by McDevitt et al..

11. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over McDevitt et al. (Pat. No. US 5,935,129).

Regarding claim 38, McDevitt et al. does not disclose a second bore formed in the expander pin and a second suture extending through the second bore. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of McDevitt et al. having a second hole and a second suture, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 29-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,733,506. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the patent does not disclose that the tissue attachment means is formed on the shaft. However, claim 7 discloses that the tissue attachment means is a bore formed in the expander pin. Therefore, it would have been obvious to one skilled in the art at the time the invention was made to add that limitation to claim 1.

14. Claims 29-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,319,252. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the patent does not disclose that the tissue attachment

means is formed on the shaft. However, claim 8 discloses that the tissue attachment means is a bore formed in the expander pin. Therefore, it would have been obvious to one skilled in the art at the time the invention was made to add that limitation to claim 1.

Response to Arguments

15. Applicant's arguments with respect to claims 1-26 and 29-63 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO form 892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNNSY SCHNEIDER whose telephone number is (571)270-7856. The examiner can normally be reached on Monday - Friday, 9:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./
Examiner, Art Unit 3733
/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733